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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,661	10/17/2005	Kenneth Kao	50680-6 /slr	4668
7380 7590 01/08/2008 SMART & BIGGAR P.O. BOX 2999, STATION D 900-55 METCALFE STREET OTTAWA, ON K1P5Y6 CANADA			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 01/08/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,661

Applicant(s)

KAO ET AL.

Examiner

Anne M. Gussow

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/19/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8, 10, 57-59, 61, 62 and 64-78 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1, 2, 4, 8, 10, 57-59, 61, 62, 64-68 and 70-78 is/are rejected.

- 7) ☒ Claim(s) 3 and 69 is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☒ Other: Sequence alignment.

DETAILED ACTION

1. Claims 1, 2, 10, 59, and 61 have been amended.
Claims 9, 60, and 63 have been cancelled.
Claims 69-78 have been added.
2. Claims 1-4, 8, 10, 57-59, 61, 62, and 64-78 are under examination.
3. The following Office Action contains NEW GROUNDS of Rejection.

Objections Withdrawn

4. The objections to the drawings are withdrawn in view of applicant's amendments to the specification.
5. The objections to the specification are withdrawn in view of applicant's amendments to the specification.
6. The objection to claim 10 is withdrawn in view of applicant's amendment to the claims.

Rejections Withdrawn

7. The rejection of claims 59 and 61 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment to the claims.

8. The rejection of claims 1-4, 8, 10, 57-59, 61, 62, and 64-68 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's amendment to the claims.

NEW GROUNDS of Objection and Rejection

Claim Objections

9. Claims 3 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 2, 4, 8, 10, 57-59, 61, 62, and 64-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 2, 4, 8, 10, 57-59, 61, 62, 65-68, and 70-78 are indefinite for reciting the phrase "predetermined cut-off value." It is not clear what the cut off value is, or what it is compared to.

b. Claims 8, 59, 61, 70, 71, and 75 are vague and indefinite in the recitation of "hPygo2" as the sole means of identifying the expressed gene referred to in claim 1.

The use of laboratory designations to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. This rejection can be obviated by amending the claims to specifically and uniquely identify hPygo2, for example, by SEQ ID NO.

c. Claims 62 and 68 are indefinite for reciting "an antibody specifically reactive to hPygo2 protein". It is not clear what the reaction is, antibodies typically bind to antigens unless they are catalytic antibodies.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 10, 62, 64-68, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramps, et al. (WO/2002/077023, filed February 1, 2002, as cited in the previous office action) in view of Kennedy (US PG PUB 2001/0016651, filed January 31, 2001).

The claims recite a kit for determining the presence or absence of a cancer wherein the cancer is at least one of cervical cancer, breast cancer, ovarian cancer and lung cancer, in a patient according to the method of claim 1, the kit comprising a reagent capable of detecting hPygo2 protein in a biological sample obtained from the patient, and instructions for using the reagent to determine whether the level of hPygo2 gene expression in the biological sample is higher compared to a predetermined cut-off value, and there from determining the presence or absence of cancer in the patient, wherein the reagent is an antibody specifically reactive to hPygo2 protein, wherein the predetermined cut-off value is the level of hPygo2 gene expression in a normal biological sample, wherein the cancer is ovarian cancer, and the biological sample comprises epithelial ovarian cells, wherein the cancer is breast cancer, and the biological sample comprises mammary cells, wherein the cancer is cervical cancer, and the biological sample comprises cervical cells, wherein the cancer is lung cancer, and the biological sample comprises lung cells.

Kramps, et al. teach an antibody that specifically binds to a Doll polypeptide (see claim 39). The human Doll polypeptide of Kramps, et al. is identical to the hPygo2 protein of the instant invention (see sequence alignment). Kramps, et al. do not teach the antibody in a kit. This deficiency is made up for in the teachings of Kennedy.

Kennedy teaches supplying antibodies, polynucleotides, or polypeptides in a kit for detecting the presence of an expression product in a biological sample (paragraph 76).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the antibody of Kramps, et al. in a kit as taught by Kennedy.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced the antibody of Kramps, et al. in a kit as taught by Kennedy because it is routine in the art to supply reagents in the form of a kit. Additionally, Kennedy teaches an intended use of the kit for detecting expression products in a biological sample, and the intended use of the instant kit is to detect hPygo2 protein in a biological sample. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the antibody of Kramps, et al. in a kit in view of Kennedy.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the references.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
January 3, 2008

/Larry R. Helms/
Supervisory Patent Examiner